UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,154	12/06/2001	Richard T. Skiffington	0656-008US6	1022

32665 7590 10/04/2004

LESLIE MEYER-LEON, ESQ.
IP LEGAL STRATEGIES GROUP P.C.
1480 FALMOUTH ROAD
P.O. BOX 1210
CENTERVILLE, MA 02632-1210

EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,154	SKIFFINGTON ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-10,12,14,15,17-19 and 21-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-10,12,14,15,17-19 and 21-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03 Oct. 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application (US Provisional Application No. 60/001,081, filed 12 July 1995) upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 8, 9 and 27-45 of this application. With respect to new claims 27-38, the instant claim language of claims 27 recites that the unit dose reagent chamber is for detection of alkaline phosphatase (AP) in a test sample. The specific reagents recited include one selected from the group consisting of i) a detergent-containing buffered solution to release alkaline phosphatase (AP) from the test sample into solution and ii) a reaction stopping solution having a pH of 8 to 11; and iii) a luciferin-luciferase or phosphatase substrate reagent. The disclosure of U.S. Provisional Application No. 60/001,081, filed 12 July 1995, discloses unit dose reagent chambers that include a cylinder having a one open end and an other opposite open end and a probe-puncturable membrane seal over the one end and the other end of the cylinder to form a sealed compartment. Provisional Application 60/001,081 also discloses that i) a microbial lysis solution and ATP stabilizer can be a reagent held in the sealed chamber; ii) a buffer optimized for luciferin-luciferase reaction can be a reagent held in the sealed chamber; or iii) luciferin-luciferase reagent tablet can be a reagent held in the sealed chamber (See the first page of the disclosure and Figure 2). As a result, of all of the possible reagents listed in claim 27, U.S. Provisional Application 60/001,081 only provides support for "a luciferin-luciferase substrate reagent". Claims 28-38 depend from claim 27 and are not supported by the disclosure of U.S.

Provisional Application No. 60/001,081 for the same reasons as set forth with respect to claim 27.

With respect to new claims 39-44, the disclosure of U.S. Provisional Application No. 60/001,081 does not support the following claim limitations recited in claim 39: i) detection of alkaline phosphatase (AP) in a test sample; ii) by color; iii) a first reagent composition to detect alkaline phosphatase by color; iv) a second reagent for use in the detection of alkaline phosphatase; v) reagent composition comprises a buffered solution to release alkaline phosphatase from the test sample. As recited with respect to claim 27 above, Provisional Application 60/001,081 only discloses the following reagents i) a microbial lysis solution and ATP stabilizer; ii) a buffer optimized for luciferin-luciferase reaction; or iii) luciferin-luciferase reagent tablet (See the first page of the disclosure and Figure 2). Claims 40-44 depend from claim 39 and are not supported by the disclosure of U.S. Provisional Application No. 60/001,081 for the same reasons as set forth with respect to claim 39.

With respect to claims 8, 9 and 45, the disclosure of U.S. Provisional Application No. 60/001,081 does not support the following claim limitations recited in claims 8, 9 and 45: i) the one end having threads for attachment of the test unit to the test apparatus. Provisional Application 60/001,081 only discloses a test unit having an open end, a closed bottom end, a probe-puncturable membrane and one or more unit dose chambers wherein a chamber comprises a cylinder having a one open end and an other opposite open end; a probe-puncturable membrane seal over the one end and the other end of the cylinder to form a sealed compartment, and a reagent composition for use in the detection of a test sample and sealed within the sealed compartment.

Note claims 1, 2, 4-10, 12, 14, 15, 17-19 and 21-45 have benefit of the filing date of U.S. Provisional Application No. 60/007,585, filed 27 Nov. 1995, since these claims are supported by the disclosure of U.S. Provisional Application No. 60/007,585.

Information Disclosure Statement

2. The information disclosure statement filed 03 Oct. 2003 has been considered and made of record.

Oath/Declaration

3. The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

The supplemental declaration filed 25 March 2004 is defective because it has not been signed.

4. Claims 1, 2, 4-10, 12, 14, 15, 17-19 and 21-45 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

Claim Objections

5. Claims 27-45 are objected to because of the following informalities:

The presentation of new claims 27-45 is not in conformance with 37 CFR 1.173(b). The presentation of new claims requires that the new claims be presented with underlining throughout the claim (See M.P.E.P. 1453). Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 8, 9 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foote et al.(WO 95/25948) in view of Wood (US 5,283,179) taken further in view of Smola et al.(US 4,004,548).

For reasons stated in section 1) above, claims 8, 9 and 45 not have benefit of the filing date of U.S. Provisional Application 60/001,081. Claims 8, 9 and 45 have an effective filing date of 27 Nov. 1995 because claims 8, 9 and 45 have benefit of U.S. Provisional Application 60/007,585, filed 27 Nov. 1995. However, the reference of Foote et al. is available as prior art under 35 USC 102(a) since it has a publication date of 28 Sept. 1995.

With respect to claims 8, 9 and 45, the reference of Foote et al. discloses unit dose chambers (12a, 12b, 12c) wherein each chamber is defined by a cylinder having two open ends sealed by probe-puncturable membrane seals (13a-13d). The reference discloses that the chambers include reagents necessary to detect ATP, i.e. extractants and reagents (See page 4, lines 6-24). The reference specifically recites luciferin-luciferase (see claim 4 of Foote et al.) as a bioluminescence agent contained in the dose chamber. Also, Figure 1 of Foote et al. discloses a test apparatus including tube (1) and well member (3) attached to tube (1). Well member (3) of the test apparatus includes a bioluminescence reagent composition (8), wherein the reagent can be luciferin-luciferase (See claim 4). The test apparatus also includes an extracting agent (6) separated from the bioluminescence reagent by a probe-puncturable membrane (7).

While the extracting agent is separated from the bioluminescence reagent by membrane (7), instant claim 8 differs by reciting that the releasing or extracting reagent is provided in a unit dose chamber that includes an open-ended cylinder sealed by probe-puncturable membranes.

The reference of Foote et al. discloses that it may be desirable to keep the swab isolated from the lysis solution to keep it dry over a long period of time (See page 6, lines 10-22). The reference of Foote et al. also discloses that it is known in the art to provide the reagents in unit dose chambers (12a-12c) that include a cylinder sealed by breakable membranes (13a-13d).

In view of this disclosure, it would have been obvious to one of ordinary skill in the art to provide the lysis reagent of the embodiment disclosed in Figure 1 of the reference of Foote et al. in a reagent compartment disclosed by Foote et al. for the known and expected result of isolating the lysis or extraction reagent from the swab prior to use and for allowing the device to be used in any orientation as suggested by the reference of Foote et al.

Claim 8 further differs by reciting that the extraction reagent is a detergent-containing buffered solution.

The reference of Wood discloses a lysing reagent known in the art that is a detergent-containing buffered solution and is compatible with luciferase assays (See column 16, lines 10-15).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the lysis reagent disclosed by the reference of Wood in the device of the primary reference for the known and expected result of providing a means recognized in the art for lysing a sample for performing a luciferase assay. With respect to claim 3, the lysis reagent includes a phosphoric acid buffer (phosphate) and non-ionic detergent (Triton X-100) (See column 16, lines 10-15).

With respect to claim 8, while the embodiment of Figure 1 discloses reagent (6) positioned within tube (1) rather than member (3), the embodiment of Figure 4 discloses that the reagent chambers can also be positioned in test unit (11).

In view of this disclosure and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide a sealed reagent chamber within member (3) rather than tube (1) for the known and expected result of providing an alternative means recognized in the art for providing reagents within a sealed chamber which are intended to be sequentially contacted with a probe member. Providing all of the reagents in member (3) would allow tube and probe member to be manufactured independent of the specific reagents employed.

With respect to the threads recited in claims 8 and 45, while the reference of Foote et al. discloses that member (3) is force-fit in the base of tube (1) (See page 4, lines 26-28), claims 8, 17, 21 and 23 differ by reciting that the test unit includes threads for attaching the test unit to the test apparatus.

The reference of Smola et al. discloses that it is known in the art that the use of screw threads for attachment of parts is an art recognized equivalent of a force-fit (See column 6, lines 49-52).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ screw threads on member (3) of the reference of Foote et al. for attachment to the tube (1) for the known and expected result of providing an alternative means recognized in the art to achieve the same result,

attaching member (3) to tube (1). Use of screw threads would facilitate both assembly and disassembly of the device while maintaining a reliable connection of the two components.

With respect to the use of a probe-puncturable membrane to seal member (3) (claims 9 and 45), the reference of Foote et al. employs membrane (7) to seal member (3). Additionally, the use of a membrane to seal the member would have been obvious for the known and expected result of providing a means recognized in the art for sealing a reagent containing vessel to protect it contents prior to use and for facilitating contacting the contents of the vessel with a sample or additional reagents when performing a assay.

10. Claims 21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al.(JP 07-59555).

The reference of Matsumoto et al. discloses a transparent test unit (1). The test unit has a closed bottom end and an open end closed by cover (6). The test unit also includes a unit dose chamber that includes a cylinder (2); probe-puncturable membranes (2a, 2b) creating a chamber holding a reagent (X) for detecting a test sample.

While the reference discloses the use of a cover (6) for the test unit, instant claim 21 differs by reciting that the test unit is sealed with a probe-puncturable membrane.

The reference of Matsumoto et al. discloses that the use of a probe-puncturable membrane (2a, 2b) is known in the art for sealing a chamber.

In view of this disclosure, it would have been obvious to one of ordinary skill in the art to seal the open end of the test unit using an additional probe-puncturable membrane in place of cover (6) for the known and expected result of providing an alternative means recognized in the

art for sealing a vessel. Use of the membrane would eliminate the need to remove cover (6) since probe device (4) would be capable of penetrating the membrane sealing the test unit.

With respect to the use of a tablet of reagent (claim 25), the reference of Matsumoto et al. discloses reagent (X) in liquid form while reagent (5) is in tablet form. In the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide reagent (X) in tablet form and reagent (5) as a liquid while maintaining the function of the assay device.

11. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al.(JP 07-59555) in view of Smola et al.(US 4,004,548).

The reference of Matsumoto et al. has been discussed above.

While the reference of Matsumoto et al. discloses that member (7) is a force-fit connection relative to the open end of test unit (1) (See Figure 4), claim 21 differs by reciting that the test unit includes threads for attaching the test unit to the test apparatus.

The reference of Smola et al. discloses that it is known in the art that the use of screw threads for attachment of parts is an art recognized equivalent of a force-fit (See column 6, lines 49-52).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ screw threads on the test unit (1) of the reference of Matsumoto et al. for attachment to member (7) for the known and expected result of providing an alternative means recognized in the art to achieve the same

result, attaching test unit (1) to member (7). Use of screw threads would facilitate both assembly and disassembly of the device while maintaining the connection of the two components.

12. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al.(JP 07-59555) in view of Bernstein (US 4,770,853).

The reference of Masumoto et al. has been discussed above.

While the reference of Masumoto et al. discloses the use of a probe-puncturable membrane and describes the membrane as "film", the reference does not specifically recite the use of "aluminum foil".

The reference of Bernstein discloses that unit dose reagent chambers (15,20) are sealed with breakable membranes (7) made of aluminum foil (See column 6, lines 3-6).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ aluminum foil as the membrane material of the reference of Masumoto et al. for the known and expected result of providing a means recognized in the art for sealing a reagent chamber while being capable of being broken by a sample swab device.

13. Claims 27, 29, 31-33, 36-39, 41, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foote et al.(WO 95/25948) in view of Abbas et al.(US 5,223,402).

For reasons stated in section 1) above, claims 27 and 39 do not have benefit of the filing date of U.S. Provisional Application 60/001,081. Claims 27 and 39 have an effective filing date of 27 Nov. 1995 because claims 27 and 39 have benefit of U.S. Provisional Application

60/007,585, filed 27 Nov. 1995. However, the reference of Foote et al. is available as prior art under 35 USC 102(a) since it has a publication date of 28 Sept. 1995.

With respect to claims 27, the reference of Foote et al. discloses unit dose chambers (12a, 12b, 12c) wherein each chamber is defined by a cylinder having two open ends sealed by probe-puncturable membrane seals (13a-13d). The reference discloses that the chambers include reagents necessary to detect ATP, i.e. extractants and reagents (See page 4, lines 6-24). The reference specifically recites luciferin-luciferase (see claim 4 of Foote et al.) as a bioluminescence agent contained in the dose chamber.

Claim 27 differs by reciting that reagents are employed for releasing and detecting phosphatase from the sample rather than ATP.

The reference of Abbas et al. discloses that it is known in the art to detect for the presence of microorganisms using an assay that employs a releasing agent for releasing enzymes from the sampled microorganisms (See column 6, lines 41-43) and exposing the released enzymes to an alkaline phosphatase substrate to produce a color reaction (See column 5, lines 39-54, and column 8, lines 3-7).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the reagents disclosed by the reference of Abbas et al. in the system of the modified primary reference for the known and expected result of providing an alternative set of reagents recognized in the art for detecting microorganisms and producing a color reaction.

With respect to claim 29, the reference of Abbas et al. discloses the use of phosphoric acid buffer and an anionic or non-ionic detergent (See column 9, lines 45-50).

With respect to claim 31, the reference of Abbas et al. discloses the use of a detergent to release AP and phosphatase substrate reagent (See the Examples).

While the extracting agent is separated from the bioluminescence reagent by membrane (7), instant claim 31 differs by reciting that the releasing or extracting reagent is provided in a unit dose chamber that includes an open-ended cylinder sealed by probe-puncturable membranes.

The reference of Foote et al. discloses that it may be desirable to keep the swab isolated from the lysis solution to keep it dry over a long period of time (See page 6, lines 10-22). The reference of Foote et al. also discloses that it is known in the art to provide the reagents in unit dose chambers (12a-12c) that include a cylinder sealed by breakable membranes (13a-13d).

In view of this disclosure, it would have been obvious to one of ordinary skill in the art to provide the lysis reagent of the embodiment disclosed in Figure 1 of the reference of Foote et al. in a reagent compartment disclosed by Foote et al. for the known and expected result of isolating the lysis or extraction reagent from the swab prior to use and for allowing the device to be used in any orientation as suggested by the reference of Foote et al.

With respect to claims 32 and 36, the reference of Foote et al. discloses a longitudinally movable probe (4,5) to puncture the membrane seals (7, 13) and discloses that the longitudinal movement of the probe can be achieved by twisting or screwing (See page 5, lines 1-3).

With respect to claim 33, while the embodiment of Figure 1 discloses reagent (6) positioned within tube (1) rather than member (3), the embodiment of Figure 4 discloses that the reagent chambers can also be positioned in test unit (11).

In view of this disclosure and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide a sealed reagent

chamber within member (3) rather than tube (1) for the known and expected result of providing an alternative means recognized in the art for providing reagents within a sealed chamber which are intended to be sequentially contacted with a probe member. Providing all of the reagents in member (3) would allow tube and probe member to be manufactured independent of the specific reagents employed.

With respect to claims 37 and 38, the reference of Abbas et al. discloses that it is known in the art to employ Tris buffer (See the Examples).

With respect to claims 39 and 43, claim 39 includes a combination of the limitations of claims 31, 32 and 33 and is met by the combination of the references discussed above with respect to these claims.

With respect to claim 41, see the discussion of claim 29 above.

With respect to claim 44, the reference of Foote et al. discloses the use of sequential unit dose chambers with reagent for releasing and detecting an analyte.

14. Claims 28 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foote et al.(WO 95/25948) in view of Abbas et al.(US 5,223,402) taken further in view of Bernstein (US 4,770,853).

The combination of the references of Foote et al. and Abbas et al. has been discussed above.

While the reference of Foote et al. discloses the use of a probe-puncturable membrane and describes the membrane as "foil", the reference does not specifically recite the use of "aluminum foil".

The reference of Bernstein discloses that unit dose reagent chambers (15,20) are sealed with breakable membranes (7) made of aluminum foil (See column 6, lines 3-6).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ aluminum foil as the membrane material of the reference of Foote et al. for the known and expected result of providing a means recognized in the art for sealing a reagent chamber while being capable of being broken by a sample swab device.

15. Claims 34, 35 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foote et al.(WO 95/25948) in view of Abbas et al.(US 5,223,402) taken further in view of Smola et al.(US 4,004,548).

The combination of the references of Foote et al. and Abbas et al. has been discussed above.

While the reference of Foote et al. discloses that member (3) is force-fit in the base of tube (1) (See page 4, lines 26-28), claims 8, 17, 21 and 23 differ by reciting that the test unit includes threads for attaching the test unit to the test apparatus.

The reference of Smola et al. discloses that it is known in the art that the use of screw threads for attachment of parts is an art recognized equivalent of a force-fit (See column 6, lines 49-52).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ screw threads on member (3) of the reference of Foote et al. for attachment to the tube (1) for the known and

expected result of providing an alternative means recognized in the art to achieve the same result, attaching member (3) to tube (1). Use of screw threads would facilitate both assembly and disassembly of the device while maintaining a reliable connection of the two components.

Allowable Subject Matter

16. Claims 1, 2, 4-7, 10, 12, 14, 15, 17-19, 23, 24, 26 and 30 define over the prior art of record, however, all the claims in this reissue application are rejected under 35 USC 251 in view of the defective declaration discussed previously.

Response to Amendment

17. The declaration under 37 CFR 1.132 filed 25 March 2004 is sufficient to overcome the rejection of claims 1, 2, 5-7, 10, 12, 14, 15, 17-19, 23, 24 and 26 based upon Foote et al. (WO 95/25948) reference since the amendments to the claims and the evidence of record establishes that the disclosure of provisional application 60/001,081, filed 12 July 1995, provides support as required of 35 USC 112, first paragraph, for the claim language of instant claims 1, 2, 5-7, 10, 12, 14, 15, 17-19, 23, 24 and 26.

18. The declaration under 37 CFR 1.132 filed 25 March 2004 is insufficient to overcome the rejection of claims 8, 9 and 45 based upon the reference of Foote et al. (WO 95/25948) as set forth in the last Office action because: While the evidence of record may establish that one of ordinary skill in the art at the time of the invention **may have recognized** that a threaded microtube may have been used in the disclosed device. The evidence of record fails to establish

to one of ordinary skill in the art at the time of the filing of the application that the instant invention expressly or inherently supported a threaded microtube. The fact that threaded microtubes were known at the time of the invention is not sufficient. The evidence must establish to one of ordinary skill in the art that the threaded microtube was part of the invention at the time of filing the application. The fact that a microtube is shown in the disclosure and that threaded microtubes were known is not sufficient to establish inherency. The microtube disclosed in the disclosure of 60/001,081 could have just as easily been a microtube without threads since these types of microtubes were also known at the time of the filing of the provisional application.

Response to Arguments

19. Applicant's arguments and amendments to the claims, see pages 13-19 and 22, filed 25 March 2004, with respect to the issues of priority have been fully considered and are persuasive. The rejections of claims 1, 2, 5-7, 10, 12, 14, 15, 17-19, 23, 24 and 26 based upon Foote et al. (WO 95/25948) reference have been withdrawn.

20. Applicant's arguments filed 25 March 2004, see pages 20-21, with respect to the issues of priority have been fully considered but they are not persuasive for the same reasons as set forth above with respect to the declaration filed 25 March 2004 under 37 CFR 1.132 (See section 18. above). The rejection of claims 8, 9 and 45 has been maintained.

21. Applicant's arguments, see page 22, filed 25 March 2004, with respect to claims 21 and 24 rejected under 35 USC 112, second paragraph, have been fully considered and are persuasive. The rejection of claims 21 and 24 under 35 USC 112, second paragraph, has been withdrawn.

22. Applicant's arguments, see pages 23-26, filed 25 March 2004, with respect to the rejection of the claims under 35 USC 102 and 103 using the reference of Foote et al. have been fully considered and are persuasive with the exception of claims 8, 9 and 45. The rejection of the claims over the reference of Foote et al. has been withdrawn with the exception of claims 8, 9 and 45. With respect to claims 8, 9 and 45 the rejections of record have been maintained for the same reasons set forth in sections (1) and (18) above.

23. Applicant's arguments filed 25 March 2004, see pages 26-27, have been fully considered but they are not persuasive.

With respect to the rejection of claims 21, 22 and 25 over the reference of Masumoto et al., Applicants argue that the rejection is improper for the following reasons. i) The reference of Matsumoto et al. does not disclose explicitly nor render obvious "a test unit that can be detachably secured to a test apparatus". ii) As a result, one of ordinary skill in the art would not be motivated to consult Smola et al. for a solution to the problem of how to detachably secure a test unit microtube to a test apparatus.

In response to comment i) above, while the reference of Masumoto et al. does not disclose a test apparatus, the top portion (3) of the device is considered to be structurally capable of being detachably secured to an test apparatus since it is capable of being detachably secured to

elements (6) or (7). Note, instant claim 21 merely recites capable of being detachably secured to a test apparatus. The claim does not positively recite the test apparatus as part of the claimed device.

In response to comment ii) above, in view of the disclosure of Masumoto et al. that includes detachably securing the vessel (1) of either element (6) or (7), one of ordinary skill in the art would be motivated to consult the reference of Smola et al. for a solution of a problem of detachably securing the vessel (1) to elements such as elements (6) or (7) of Masumoto et al. As a result of the modification as suggested by the combination of the references of Masumoto et al. and Smola et al., a structure would result in a vessel with a threaded end portion that would be capable of being detachably secured to a test apparatus.

In response to applicants comments concerning what structures of Matsumoto et al. correspond with applicants' detachable "test unit" and applicants' "test apparatus", element(s) (1 and/or 3) can be considered to structurally correspond with applicants' "test unit". No structure disclosed by the reference of Matsumoto et al. corresponds to applicants' "test apparatus". Instant claim 21 does not positively recite the "test apparatus" are part of the claimed device. The Examiner has merely established that the structure of Matsumoto et al. that corresponds to applicants' "test unit" would be capable of being detachably secured to a "test apparatus" since the same structure is capable of being detachably secured to elements (6) or (7).

Conclusion

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H. Beisner
Primary Examiner
Art Unit 1744

WHB